UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,080	11/21/2001	Gregg B. Morin	018/258C	2136

22869 7590 01/14/2004

GERON CORPORATION
230 CONSTITUTION DRIVE
MENLO PARK, CA 94025

EXAMINER	
WALICKA, MALGORZATA A	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,080	MORIN, GREGG B.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Nov.3,2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet.*

Continuation of Attachment(s) 6). Other: Notice to Comply, Errors Corrected by STIC, two versions of Raw Sequence Listing

The Response to Restriction Requirement filed on Nov 3, 2003 is acknowledged. The amendment to claims 1-3 and new claims 13-20 are acknowledged.

Detailed Action

1. Restriction/ election

Applicant's election with traverse of Group I, directed to a protein, peptide, or peptide mimetic having a sequence comprising 10 consecutive amino acids in SEQ ID NO: 2, or comprising 10 consecutive amino acid encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1 wherein the encoded peptide contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-66, 748-766, 1055-1071, 1084-116 of SEQ ID NO:2 is acknowledged.

In traversing the restriction issued by the previous examiner on 10/03/2003, applicants state the search and examination of the application is limited "with respect to fragments and variants of human TERT (a single species) in order to consider the patentability of the full scope of all the pending claims in this application", and request withdrawal of the restriction requirement.

Applicants' argument has been fully considered but is found not persuasive for the following reasons.

Firstly, human telomerase reverse transcriptase (TERT) is not a single species, but a large genus of versatile species. TERT identified by SEQ ID NO: 2 is a single

species. The claims are directed not only to TERT polypeptide genus, as in case of new claim 13, but also to a larger genus of polypeptides. This genus (genus A) encompasses any of the at least 10 amino acid fragment of SEQ ID NO: 2 is not limited to human TERT and its variants, but includes the sequences that origin in less than 1% from human TERT. The genus of claim 1 part b) i.e., the genus encompassing SEQ ID NO: 3, 4 and 5 (or 10 amino acids thereof) is included in genus A, because SEQ ID NO: 3, 4, and 5 are encompassed in SEQ ID NO: 2 (see the Applicants paper showing that SEQ ID NO: 3, 4, and 5 are embedded in the human TERT amino acid sequence of SEQ ID NO: 2).

The genus of polypeptides that encompasses any polypeptide that comprises at least 10 consecutive amino acid from the polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1 wherein the encoded peptide contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-66, 748-766, 1055-1071, 1084-116 of SEQ ID NO:2 (genus B) has the scope smaller and only partially overlapping with the scope of genus A. The amino acid sequence obtained from SEQ ID NO: 2 by deleting any of the indicated fragments is not comprised anymore in SEQ ID NO: 2. For that reasons the search of the claims cannot be limited to the search of SEQ ID NO: 2.

Upon reconsideration of the claims as amended the restriction requirement made by the previous examiner and mailed on Oct 10, 2003 is withdrawn; a new restriction requirement is as follows.

Restriction to one of the following invention is required under 35 U. S. C. 121:

Group I. Claims 1, 2, 5, 6, 7 (all in part), claims 8 and 9, claims 13, 14 and 15 (all in part), claims 18, 19 and 20, claim 10-12 (both in part) drawn to protein, peptide or peptide mimetic comprising at least 10 consecutive amino acid in SEQ ID NO: 2, in particular at least 10 consecutive amino acids in SEQ ID NO: 4, and a sequence comprising SEQ ID NO: 3 and 5, and to the method of use for inhibiting telomerase catalytic activity; classified in class 424 subclass 94.5.

Group II. Claims 1, 2 (both in part), 3, 4, claims 5, 6, 7, 13, 14, 15 (all in part), 16, and 17, claims 1-12 (both in part) drawn to polypeptide that comprises at least 10 consecutive amino acid from the polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1 wherein the encoded peptide contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-66, 748-766, 1055-1071, 1084-116 of SEQ ID NO:2, and to the method of use for inhibiting telomerase catalytic activity; classified in class 424 subclass 94.5.

Group I and II are directed to two genera of chemical compounds, and methods of their use, wherein the scopes of said genera are overlapping but not coextensive.

Search for the at least 10 amino acid residues of Group II involves peptides that are not encompassed by Group I, and vice versa. Thus, searches required for the separate inventions are not coextensive and restriction between Group I and Group II for examination purposes as indicated is proper.

In their Remarks applicants write, "Claim 13 is generic claim that links products in all four groups [according to the previous restriction]." This however is not the case, because the scope of claim 13 is narrower than the scope of previous Groups I-IV or current Groups I and II. Claim 13 is directed to a protein, peptide, or peptide mimetic, that is a dominant negative mutant of human telomerase reverse transcriptase having a means for inhibiting telomerase activity. Group I and II encompass not only dominant negative mutants of human telomerase.

Applicant is advised that the replay to this requirement to be complete must include election of the invention to be examined, even though the requirement be traversed (37 CFR 1.143).

2. Lack of compliance of nucleotide sequence disclosure with 37 C.F.R. 1.821-1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply

With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. The CRF filed on Nov. 21, 2001 contains errors as indicted in the Raw Sequence Listing dated 11/282001. These obvious errors were corrected on Dec. 3, 2001 by STIC; see the attached copy of Errors Corrected sheet. The paper copy of the sequence listing is still erroneous.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner

01-12-04

DAVID STEADMAN
PATENT EXAMINER

Application No.: 09/990,080
NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING

NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the Sequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up Raw Sequence Listing.

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☒ 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the Sequence Listing.

☒ An initial or **substitute paper** copy of the Sequence Listing, as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For Patent software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE